

REMARKS

Applicant thanks the Examiner for consideration of the Information Disclosure Statement mailed September 3, 2003 and the Supplemental Information Disclosure Statement mailed September 30, 2003.

Claims 1, 2, 5, 7-14, 20-27 and 30-35 have been rejected under 35 U.S.C. §102(b) as being anticipated by Barath (U.S. Patent No. 5,196,024), Vigil et al. (U.S. Patent No. 5,320,634), Kaplan et al. (U.S. Patent No. 5,336,178), and/or Klein (U.S. Patent No. 5,863,284), and in further view of Baskin (U.S. Patent No. 2,854,983), Claiman and Chu et al. (U.S. Patent No. 5,967,984). Applicant is unable to find a Claiman reference in the file history, and thus assumes that the Examiner is referring to either Clayman '746 (U.S. Patent No. 5,628,746) or Clayman '679 (U.S. Patent No. 5,904,679). Reconsideration of these claims is respectfully requested.

Barath, Vigil et al., Kaplan et al. and Klein have been cited in detail in the Amendment filed May 9, 2005.

Newly cited Baskin discloses inflatable catheters that are adapted to be advantageously employed in various body drainage procedures, especially useful in various simple visceral drainage procedures, including drainage of the bladder, gastrointestinal viscera, peritoneal, thoracic and other body regions, preoperative drainage procedures and postoperative drainage procedures. Col. 1, lines 15-25. In Figs. 1 through 4, Baskin discloses a catheter 10 having a flexible tubular member 12. The forward end portion of the tubular member is provided with a plurality of entrance openings 18 which establish communication between passage 14 and the exterior of the catheter. An inflatable bag 24 encircles tubular member 12 and is positioned rearward of openings 18. This bag has a pair of annular end extensions 26 which are cemented or otherwise secured to the tubular member to form a hermetical seal therewith. The catheter is provided with a means or unit 30 to prevent obstruction of openings 18 when the catheter is in use. Unit 30 comprises a flexible tubular device 32 which extends over and along the forward end portion of tubular member 12 and bag 24. Device 32 is closed at its forward end 34 and is slotted so as to obtain a plurality of flexible strut strips or elements 36. In its mode of operation, the bag is inflated by air admitted through conduit 22, passage 20 and duct 28. This draws strut elements 36 taut and in spaced relation to entrance openings 18, thereby preventing obstruction of these openings by body tissue or the like, but permitting free flow of bladder fluids through the openings and central passage. Col 2, line 47 through Col. 3, line 20.

Clayman '679 discloses a dilatation catheter assembly, generally designated 10, that may be used for dilating a body vessel or conduit, such as a ureter or urethra, to treat a blockage or other obstruction. The main elements of catheter assembly 10 are: an adapter 11 that defines the proximal end 12 of the assembly 10 and a site for various ports to the assembly 10; a catheter body 13 having a triple lumen 14 (FIG. 2); an inflatable balloon or bladder member 15; a stiffening guide wire or stylet 16 that extends longitudinally within one of the three lumens 14 of the catheter body 13; and a cutting element or electrode 17, preferably a radiofrequency cutting element 17 activatable by a radiofrequency power source 21. The electrosurgical cutting element 17 is in the nature of a wire which extends generally parallel to the longitudinally-extending inflatable bladder 15. Col. 5, lines 23-38. In operation, the bladder member 15 is inflated. Such inflation causes the cutting element 17 to move radially outwardly as the bladder surface expands radially until the cutting element 17 contacts the surrounding tissue. Col. 7, lines 38-40. Continued radial expansion of the bladder member 15 positions the cutting element 17 and causes the bladder member 15 to exert pressure on the tissue thereby subjecting the tissue to a substantially uniform tangential tension. Then a radiofrequency current can be passed through the cutting element 17. Col. 7, lines 46-51. FIGS. 3-6 depict another dilatation catheter assembly of the invention. The distal end of the catheter is defined by a closed end catheter tube 32 which carries an inflatable, preferably inextensible, bladder member 33 on its exterior. A pair of expandable ring-shaped members 37, 38 extend around the exterior of the bladder member 33 near the distal and proximal ends thereof. One or more cutting elements 39 are affixed between the rings so that they extend longitudinally and outwardly therefrom. Col. 8, lines 8-23.

Cayman '746 discloses structure similar to Cayman '679.

Chu et al. appear to disclose structure similar to Cayman '679 and Cayman '746. More specifically, Chu et al. disclose a catheter 10 that includes a flexible catheter body 12 and a dilatation balloon 14 disposed on a distal portion of catheter body 12. Col. 3, lines 59-60. Catheter body 12 further includes a wire lumen 28 within which a radio frequency (RF) cutting wire 30 (i.e., an electrode wire) is disposed. A distal portion 30a of the RF cutting wire extends through a first catheter body aperture 12a, along a portion 14a of the external surface of balloon 14, and through a second catheter body aperture 12c. Col. 4, lines 3-8.

Amended Claim 1 is patentable by calling for a balloon catheter for performing an angioplasty procedure on a lesion in a vessel comprising a flexible elongate catheter shaft having

proximal and distal extremities, a balloon secured to the distal extremity of the catheter shaft and having proximal and distal extremities and having an interior and an inflatable portion movable between deflated and inflated conditions, the catheter shaft having a balloon inflation lumen extending from the proximal extremity to the distal extremity of the catheter shaft and opening into the interior of the balloon, a fitting for supplying an inflation medium to the inflation lumen for causing movement of the inflatable portion of the balloon from the deflated condition to the inflated condition, the inflatable portion of the balloon having an outer surface which moves outwardly radially upon inflation of the balloon and at least one flexible elongate element extending over the outer surface of the balloon from the proximal extremity to the distal extremity of the balloon, said flexible elongate element having a proximal extremity coupled to the catheter shaft proximal of the inflatable portion of the balloon and a distal extremity, an elastic member distinct from the flexible elongate element for coupling the distal extremity of the flexible elongate element to the catheter shaft distal of the inflatable portion of the balloon and for permitting the flexible elongate element to move radially outward as the balloon is inflated whereby expansion of the balloon causes movement of the flexible elongate element into engagement with the lesion to form a longitudinal channel in the lesion.

None of newly cited Baskin, Clayman '679, Clayman '746 or Chu et al discloses a balloon catheter having a flexible elongate element and an elastic member distinct from the flexible elongate element for coupling the distal extremity of the flexible elongate element to the catheter shaft distal of the inflatable portion of the balloon and for permitting the flexible elongate element to move radially outward as the balloon is inflated.

Claims 2, 5, 7-14 and 20 depend from Claim 1 and are patentable for the same reasons as Claim 1 and by reason of the additional limitations called for therein.

Claim 21 is patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel of the type set forth therein having, among other things, at least one flexible elongate element secured to the catheter shaft proximal and distal of the inflatable portion so as to extend longitudinally over the inflatable portion of the balloon and be in longitudinal tension over the inflatable portion of the balloon. None the newly cited references discloses at least one flexible elongate element secured to the catheter shaft proximal and distal of the inflatable portion so as to extend longitudinally over the inflatable portion of the balloon and be in longitudinal tension over the inflatable portion of the balloon.

Claims 22-24 depend from Claim 21 and are patentable for the same reasons as Claim 20 and by reason of the additional limitations called for therein.

Claim 25 is patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel of the type set forth therein in which, among other things, at least one of the proximal and distal extremities of the flexible elongate element is formed of an elastic material distinct from the material of the remainder of the flexible elongate element to permit stretching of the flexible elongate element during inflation of the balloon. None of Baskin, Clayman '679, Clayman '746 or Chu et al discloses a balloon catheter of the type called for in Claim 24 in which at least one of the proximal and distal extremities of the flexible elongate element is formed of an elastic material distinct from the material of the remainder of the flexible elongate element to permit stretching of the flexible elongate element during inflation of the balloon.

Claim 26-27 depend from Claim 25 and are patentable for the same reasons as Claim 24 and by reason of the additional limitations called for therein.

Claim 30 is patentable for the same reasons as Claim 1 by calling for a balloon catheter for performing medical procedure on a lesion in a vessel having, among other things, an elastic member distinct from the flexible elongate member for securing of the second extremity of the flexible elongate member to the catheter shaft for permitting the flexible elongate member to move radially outward as the balloon is inflated.

Claim 31-35 depend from Claim 30 and are patentable for the same reasons as Claim 30 and by reason of the additional limitations called for therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help

further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

DORSEY & WHITNEY LLP

A handwritten signature in black ink, appearing to read 'E. Bachand', is written over the firm name.

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